SigmaPace™ 1000 External Pacemaker Analyzer

Overview

The SigmaPaceTM 1000 is a powerful handheld analyzer with a comprehensive range of test suites, measurement algorithms and test loads – as specified by the external pacemaker manufacturers – to fulfill your testing requirements both quickly and efficiently.

Standard Features

- Unique full-featured biomedical test product
- Tests for both transcutaneous and transvenous external pacemakers
- Full range of user-selectable measurement algorithms and test loads for external pacemakers
- Dual-channel signal acquisition for capturing synchronous AV-sequential pulse data
- Interactive pacemaker and ECG simulation with 5-lead output
- Large 21-character x 8-line alphanumeric LCD readout
- Exclusive readout "HOLD" function
- Exclusive SigmaPaceTM 1000 test features: DC static/dynamic leakage, and current drain

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Specifications	
Modes of Operation	Manual Remote (via standard RS232 serial port)
User Interface	**Display:** - LCD readout - 21 characters X 8 lines - Brightness/viewing angle adjustment **Keys:** Eight push buttons (F-2, F-3 [UP arrow], F-4 [UP arrow], two DOWN arrows, ESCAPE, and ENTER)
Transcutaneous Pacer Tests:	**Output Pulse Measurement** **Current:** - Ranges: 4.00 mA to 9.99 mA; 10.0 mA to 99.9 mA; 100 mA to 250 mA - Accuracy: ± 2 % of reading or ± 50 µA (whichever is greater) **Rate:** - Ranges: 5.0 PPM to 99.9 PPM; 100 PPM to 300 PPM - Accuracy: ± 0.5 % of reading or ± 0.3 PPM (whichever is greater) **Width:** - Ranges: 1.00 mS to 9.99 mS; 10.0 mS to 99.9 mS - Accuracy: ± 0.5 % of reading or ± 14 µS (whichever is greater) **Energy:** - Ranges: 1 µJ to 999 µJ; 1 mJ to 999 mJ; 1.00 J to 1.99 J - Accuracy: 5 % of reading/computation **Demand and Asynchronous Mode Tests**

	Waveform (Physiological Simulation):	- Normal sinus rhythm (NSR) - Complete P-QRS-T complex
	Amplitude:	1.0mVpeak (lead I)
	Modes of Operation:	- Underdrive: NSR @ 85 % of pulse interval/rate - Overdrive: NSR @ 115 % of pulse interval/rate - Auxiliary Control: NSR adjustable in 1-BPM increments - Auxiliary Rate Range: Underdrive 10 BPM (min); overdrive 300 BPM (max)
	Active Outputs:	5-lead ECG; ventricular test load; high-level ECG jack
	Pacemaker Compatibility:	- Pulse Rates: 30 to 200 PPM - Intended Types: Demand: VVI (pace and sense); async: VOO (pace)
	Amplitude Sensitivity Test Selections: R, S and T Waves	- Rate: 30 to 200 PPM - Test Loads: (30) 50 Ω to 1550 Ω in 50-Ω steps
	Waveforms:	Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ)
	Amplitude:	- Range: 0.05 mVpeak to 5.0 mVpeak - Accuracy: ± 5 % of setting Resolution: 0.05-mV steps (0.05 to 0.95 mVpeak); 0.50-mV steps (1 to 5 mVpeak)
	Width:	- Range: 0.15 mS to 300 mS - Accuracy: ± 5 % of setting - Selections: 50 - Resolution: 0.05-mS steps (0.15 to 0.95 mS); 1-mS steps (1 to 19 mS);
	5-mS steps (20 to 95 mS)	25-mS steps (100 to 300 mS)
	Active Outputs:	5-lead ECG; ventricular test load; high-level ECG jack
	Pacemaker Compatibility:	- Pulse Rates: 30 to 200 PPM - Intended Type: VVI (pace and sense)
	Noise Immunity/Line Frequency Test	
	Waveform:	Sine wave - Frequency: 50 and 60 Hz - Accuracy: 0.5 Hz
	Amplitude Testload Output:	- Range: 0 (OFF) to 10 mVpeak-to-peak - Accuracy: ± 5 % of setting - Resolution: 0.5-mVpeak-to-peak steps - Settings: (30) 50 Ω to 1550 Ω ± 1 %
	5-lead ECG Output:	- Range: 0 (OFF) to 10 mVpeak-to-peak - Accuracy: ± 5 % of setting - Resolution: 0.50-mV steps - Reference: Lead I (RA to LA)
	Active Outputs:	5-lead ECG; ventricular test load
	Paced Refractory Period Test (PRP)	
	Range:	20 mS to 500 mS - Accuracy: 5 % of reading or 1 mS (whichever is greater)
	Physiological Simulation:	- Selection: Single pulse, R Wave, SSQ - Pulse Width: 40 mS
	Outputs:	5-lead ECG; ventricular test load
	Pacemaker Compatibility:	- Pulse Rates: 30 to 200 BPM - Intended Type: VVI (pace and sense)
	Sensed Refractory Period Test (SRP)	
	Range:	15 mS to 500 mS
	Accuracy:	± 5 % of reading or ± 1 mS (whichever is greater)
	Physiological Simulation:	- Selection: Double pulse, R Wave, SSQ - Pulse Width: 40 mS - Amplitude: 1 mVpeak lead I
	Active Outputs:	5-lead ECG; ventricular test load
	Pacemaker Compatibility:	- Pulse Rates: 30 to 200 BPM - Intended Type: VVI (pace and sense)

	Test Loads	
	Transcutaneous Pacer:	- Selections: (31) 50 Ω to 1550 Ω in 50-Ω steps - Accuracy: ± 1 % of selection - Power Rating: 5 W (average); 40 W (peak) @ 1000 Ω
	Input Defibrillation Protection:	- Type: Internal spark gap Episode Limit: 5 pulses @ 360 J (10 seconds min between discharges) - Life Limit: 250 pulses @ 360 J
Transvenous Pacer Tests:	**Output Pulse Measurement**	
	Current:	- Ranges: 0.05 mA to .999 mA (available single channel only); 1.00 mA to 9.99 mA; 10 mA to 30 mA - Accuracy: ± 2 % of reading or ± 50 µA (whichever is greater) - Polarity Indicator: + or -
	Rate:	- Ranges: 10.0 PPM to 99.9 PPM; 100 PPM to 999 PPM - Accuracy: ± 0.5 % or 0.3 PPM (whichever is greater)
	Width:	- Ranges: 0.020 mS to .999 mS; 1.00 mS to 9.99 mS; 10.0 mS to 99.9 mS - Accuracy: 0.5 % or ± 14 µS (whichever is greater) - Resolution: ± 1 LSD or ± 4 µS (whichever is greater)
	Voltage:	- Ranges: (available single channel only) 0.050 Vpeak to .999 Vpeak; 1.00 Vpeak to 9.99 Vpeak; 10 Vpeak to 30 Vpeak - Accuracy: ± 2 % of reading or ± 0.05 Vpeak (whichever is greater) - Polarity Indicator: + or -
	Energy:	- Ranges: (available single channel only) 1 nJ to 999 nJ; 1 µJ to 999 µJ - Accuracy: ± 5 % of reading/computation
	Display Formats:	Atrial channel only; ventricular channel only; both A + V channels
	AV Interval (Delay Time)	
	Measurement Ranges:	10.0 mS to 99.9 mS; 100 mS to 999 mS
	Start Point:	Atrial pulse leading edge
	Stop Point:	Ventricular pulse leading edge
	Accuracy:	1 % of reading/computation
	Demand/Async Mode Tests	
	Channels:	Single and dual
	Waveform:	Sine square (SSQ)
	Atrial Output:	Simulated P Wave - Width: 30 mS - Amplitude: 2.0 mVpeak
	Vent Output:	Simulated R Wave - Width: 40 mS - Amplitude: 2.5 mVpeak
	AV Interval:	90 mS (fixed)
	Interactive Simulated Rates:	- Default Settings: Underdrive = NSR @ 85 % of pulse interval/rate; overdrive = NSR @ 115 % of pulse interval/rate - Manual: NSR simulations adjustable in 1-BPM increments - Limits: Underdrive (min) = 10 BPM; overdrive (max) = 300 BPM
	Output:	Ventricular channel test load; atrial channel test load
	Pulse Rate:	30 to 200 PPM
	Intended Pacemaker Types:	- Demand: VVI (V-channel pace and sense); AAI (A-channel pace and sense);
	DDD (dual-channel pace and sense)	- Async/Continuous: VOO (V-channel pace and sense); AOO (A-channel pace and sense); DOO (dual-channel pace and sense)
	Amplitude Sensitivity Test	
	Operation:	Single-channel operation only (atrial or ventricular)
	Atrial Channel (Physiological	- Selection: P Wave

Simulation):	
	- Rate: 30 to 120 BPM - Timing: Waveform delayed by 80 % of the pulse-to-pulse interval or 400 mS (whichever is shorter) - Active Output: Atrial test load
Available Test Loads:	200 Ω, 500 Ω (default setting) and 1000 Ω ± 1 %
Waveform Selections:	Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ) (default setting); asymmetrical triangle (ISO) – fixed width: 2 mS rise time/13 mS fall time
Sensitivity Waveform Amplitude:	
- Test Load Selection:	500 Ω (default setting) -- Range: 0.05 mVpeak to 50.0 mVpeak -- Accuracy: ± 5 % of setting --Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1 to 50 mVpeak)
- Test Load Selection:	200 Ω -- Range: 0.05 mVpeak to 20.0 mVpeak -- Accuracy: ± 5 % of setting -- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1 to 20 mVpeak)
- Test Load Selection:	1000 Ω -- Range: 0.05 mVpeak to 100 mVpeak-to-peak -- Accuracy: ± 5 % of setting -- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1.0 to 49.5 mVpeak); 05.0 mVpeak (50 to 100 mVpeak) - Default Setting: 2.0 mVpeak
Widths:	- Range: 0.15 mS to 95.0 mS - Accuracy: ± 5 % of setting - Resolution: 0.05 mS (0.15 mS to 0.95 mS); 1 mS (1 mS to 19 mS); 5 mS (20 mS to 95 mS)
Intended Pacemaker Types:	AAI (atrial pace and sense) - Pulse Rates: 30 to 200 PPM
Ventricular Channel (Physiological Simulation):	- Selection: R Wave, S Wave and T Wave
	- Rate: 30 to 120 BPM - Timing: Waveform delayed from the ventricular demand pacemaker pulse by 80 % of the pulse-to-pulse interval or 400 mS (whichever is shorter) - Active Output: Selected ventricular test load
Waveform Selections:	Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ) (default setting); asymmetrical triangle (ISO) – fixed width: 2 mS rise time/13 mS fall time
Available Test Load(s):	200 Ω, 500 Ω (default setting) and 1000 Ω ± 1 %
Amplitude:	
- Pacer Load Selection:	500 Ω -- Range: 0.05 to 50.0 mVpeak -- Accuracy: ± 5 % of setting -- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1 to 50 mVpeak)
- Pacer Load Selection:	200 Ω -- Range: 0.05 mVpeak to 20.0 mVpeak -- Accuracy: ± 5 % of setting -- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1 to 20 mVpeak)
- Pacer Load Selection:	1000 Ω -- Range: 0.05 mVpeak to 100 mVpeak-to-peak -- Accuracy: ± 5 % of setting -- Resolution: 0.05 mVpeak (0.05 to 0. 95 mVpeak); 0.50 mVpeak (1.0 to 49.5 mVpeak); 05.0 mVpeak (50 to 100 mVpeak) - Default Setting: 2.5 mVpeak
Widths:	- Range: 0.15 mS to 300 mS - Accuracy: ± 5 % of setting

	- Resolution: 0.05 mS (0.15 to 0.95 mS); 1 mS (1 to 19 mS); 5 mS (20 mS to 95 mS); 25 mS (100 mS to 300 mS)
Intended Pacemaker Type(s):	VVI (atrial pace and sense only) - Pulse Rates: 30 to 200 PPM
Noise Immunity Test	
Channels:	Single, atrial or ventricular only
Waveform:	Sine wave
Frequency:	50 and 60 Hz
Accuracy:	± 0.5 Hz
Active Output(s):	Atrial- or ventricular-channel test load
Output Selections:	Atrial channel only; ventricular channel only
ECG Signal:	ECG signal can be added to the selected channel.
Atrial:	1 mVpeak
Ventricular:	1.5 mVpeak
Noise Line Amplitude:	
- Pacer Load Selection:	500 Ω -- Range: 0 (OFF) to 100 mVpeak-to-peak -- Accuracy: ± 5 % of setting -- Resolution: 5-mVpeak-to-peak steps
- Pacer Load Selection:	200 Ω -- Range: 0 (OFF) to 40 mVpeak-to-peak -- Accuracy: ± 5 % of setting -- Resolution: 5-mVpeak-to-peak steps
- Pacer Load Selection:	1000 Ω -- Range: 0 (OFF) to 200 mVpeak-to-peak -- Accuracy: ± 5 % of setting -- Resolution: 5-mVpeak-to-peak steps
Refractory Period Test (Atrial Channel)	
Test Selections:	Paced refractory period; sensed refractory period
Period:	20 to 500 mS
Accuracy:	± 5 % of reading (or ± 1 mS, whichever is greater)
Resolution:	± 1 LSD
Physiological Simulation:	- Selection: Square wave (default setting) - Atrial Channel: Simulated P Wave - Width: 1 mS - Amplitude: 20 mVpeak - Active Outputs: Atrial channel (4mm banana jacks) only
Additional Waveform Selections:	Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ); asymmetrical triangle (ISO) – fixed width: 2 mS rise time/13 mS fall time
Amplitude:	- Range: .05 mVpeak to 50.0 mVpeak - Accuracy: ± 5 % of setting - Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1.0 to 49.5 mVpeak)
Width:	- Range: 0.15 mS to 95.0 mS - Accuracy: ± 5 % of setting - Resolution: 0.05 mS (0.15 to 0.95 mS); 1 mS (1 to 19 mS); 5 mS (20 to 95 mS)
Active Outputs:	Atrial channel (4mm banana jacks) only
Intended Pacemaker Types:	AAI (atrial pace and sense only)
Pacemaker Rates:	30 to 200 PPM
Available Test Load:	500 Ω ± 1 %
Refractory Period Test (Ventricular Channel)	
Test Selections:	Paced refractory period; sensed refractory period
Period:	20 to 500 mS
Accuracy:	± 5 % of reading (or ± 1 mS, whichever is greater)
Resolution:	± 1 LSD
Display Format:	3 digits
Physiological Simulation:	- Selection: Square wave (default setting) - Ventricular Channel: Simulated R Wave - Width: 1 mS - Amplitude: 20 mVpeak

	- Active Outputs: Ventricular channel (4mm banana jacks) only
Additional Waveform Selections:	Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ); asymmetrical triangle (ISO) – fixed width: 2 mS rise time/13 mS fall time
Amplitude:	
- Pacer Load Selection:	500 Ω -- Range: .05 mVpeak to 50.0 mVpeak -- Accuracy: ± 5 % of setting -- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1.0 to 49.5 mVpeak)
- Default setting:	20 mVpeak
Width:	- Range: 0.15 mS to 300.0 mS - Accuracy: ± 5 % of setting - Resolution: 0.05 mS (0.15 to 0.95 mS); 1 mS (1 to 19 mS); 5 mS (20 to 95 mS); 25 mS (100 to 300 mS) - Default setting: 30 mS
Intended Pacemaker Types:	VVI
Pacemaker Rates:	20 to 200 PPM
DC Leakage Current	
Measurement Range:	00.1 µA to 99.9 µA
Input Polarity:	Positive and negative
Resolution:	1 LSD (0.1 µA)
Display Format:	3 digits
Test Selections:	- Static: Continuous (power OFF) - Dynamic: Gated (power ON)
Test Load/Input Configurations:	- Atrial+ and atrial- - Ventricular+ and ventricular– - Atrial+ and ventricular+
Baseline/Test Selection:	500 Ω
Dynamic Test Gating Algorithm:	Measurement made 400 mS prior to the pacemaker pulse leading edge; 16 measurements averaged at a 4 mS rate for a total of 64 mS
Specified Applied Pacemaker Rate:	80 PPM
Current Drain Test	
DC Current Ranges:	0.100 mA to 0.999 mA; 1.00 mA to 9.99 mA; 10.0 mA to 99.9 mA
Polarity:	Positive or negative
Indicator:	+ or – symbol
Resolution:	± 1 LSD
Display Format:	3 digits plus decimal point
Accuracy:	± 5 % of reading ± 10 µA
Input DC Voltage:	- Nominal: ± 9 V - Range: 5.0 V to 10.5 V - Input Protection: Short-circuit protection - Protection Type: Internal in-line fast-acting 1⁄2 A fuse
Selectable Testloads:	200 Ω, 500 Ω, and 1000 Ω
Battery Test Fixture:	9 V battery supply included, to facilitate connection of analyzer to recessed battery terminals within Medtronic 5388 and 5348 Temporary Pacemakers
Test Loads	
Atrial Channel:	- Selections: 200 Ω, 500 Ω, and 1000 Ω - Accuracy: ± 1 % of selection - Power Rating: 2 W
Ventricular Channel:	- Selections: 200 Ω, 500 Ω, and 1000 Ω - Accuracy: ± 1 % of selection - Power Rating: 2 W
Tracking:	Identical atrial and ventricular channel settings
Input Defibrillation Protection:	- Type: Internal spark gap - Episode Limit: 5 pulses @ 360 J (10 seconds min between discharges) - Life Limit: 250 pulses @ 360 J
Long-Term Test	

	Test Configuration:	- Transvenous Pacer: Atrial or ventricular channel only - Transcutaneous Pacer: Ventricular channel - Pulse Count Range: 999,999 (max) - Rate: 2 % to 20 % (default setting, 10 %) - Amplitude: 2 % to 20 % (default setting, 10 %) - Test Time (max): 999:59:59 (hhh:mm:ss) - Maximum Error Count: 200 - Test Termination: Manual; or upon max error count - Testloads: 200 Ω, 500 Ω, and 1000 Ω
	Interactive Pacer ECG Simulation	
	Simulation of demand, continuous, noncapture, and nonfunction patient	-ECG activity
	Additional user -selectable parameters:	- NSR Heart Rate: Asystole and 20 to 250 BPM (1-BPM steps) - NSR PR Interval: 0.05 to 0.30 s (6 settings)
	Pacemaker Capture/Threshold:	- Transcutaneous: 10 to 250 mA (10-mA steps) - Transvenous: 1 to 25 mA (1-mA steps)
	General Specifications	
	Serial Port:	- Type: RS232 - Connector Type: DB-9 (male) - Baud Rates: 2400, 9600, and 19200 - Data Control: Xon/Xoff
	Power Requirements:	- External battery charger source/power supply - 100 to 240 Vac, 50/60 Hz operation - Auto power-off feature during battery operation
	Battery Life:	20 hours (min)
	Environmental Specifications	
	Temperature Range:	- Operating: 15 °C to 35 °C (59 °F to 95 °F) - Storage: 0 °C to 50 °C (32 °F to 122 °F)
	Humidity Range:	< 90 % noncondensing
	Dimensions	
	Size:	8” L X 4” W X 2” H (approx) (203 mm L X 101 mm W X 50 mm H)
	Weight:	2 lb (approx) (0.90 kg)
	CE Mark	
	User Safety:	
	EMC:	EN61326-1.1997
	Conforms to:	UL STD 3101-1
	Certified to:	CAN/USA STD C22.2 No.1010
	ETL Listed	
	Device has received FDA 510(k) clearance (on file)	